Section 5 – 510(k) Summary

K090193

SEP 25 2009

General Information

Owner's Name:	Concert Medical, LLC
Address:	77 Accord Park Drive Norwell, MA 02061
Telephone Number:	(781) 871-7882
Fax Number:	(781) 871-6657
Contact Person:	Nancy Martin, VP of Operations & Regulatory Affairs
Subject Device Name:	Conductor Coronary Guidewire
Trade Name:	Conductor Coronary Guidewire
Common/Usual Name:	Coronary Guidewire
Classification Name:	DQX – Wire, Guide, Catheter 21 CFR 870.1330; Class II
Predicate Device Name:	Galeo Guidewire
Trade Name:	Galeo Guidewire
Common/Usual Name:	Coronary Guidewire
Classification Name:	DQX – Wire, Guide, Catheter 21 CFR 870.1330; Class II
Premarket Notification:	K001736 (Galeo Hydro Guidewire), SE date August 2, 2000 K982272 (Galeo Guidewire), SE date January 8, 1999

Device Description
The Concert Medical Conductor coronary guidewire consists of a flexible wire that is available with silicone or hydrophilic coating. The wire is intended to guide the placement of intravascular catheters with compatible lumens during PTCA or other therapeutic or diagnostic procedures.

Indications for Use
For use in vascular interventional procedures to facilitate placement of catheters within the coronary arteries.

Performance Testing
Performance data demonstrated that the Concert Medical Conductor guidewire is substantially equivalent to the predicate device and/or met pre-determined acceptance criteria. The risks associated with use of the new device were found acceptable when evaluated by FMEA.

Bench tests performed in accordance with FDA's January 1995 *Coronary and Cerebrovascular Guidewire Guidance* included assessments of performance data. Biocompatibility testing was performed on the patient-contacting materials present in the Conductor guidewire in accordance with ISO 10993-1.

Conclusion
The Concert Medical Conductor coronary guidewire meets all the pre-determined acceptance criteria of the testing performed to confirm safety and effectiveness; the Conductor guidewire is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Concert Medical, LLC
C/O Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

SEP 25 2009

Re: K090193
Trade/Device Name: Conductor Coronary Guidewire
Regulation Number: 21 CFR 870.1330
Regulation Name: Wire, Guide, Catheter
Regulatory Class: Class II
Product Code: DQX
Dated: September 14, 2009
Received: September 16, 2009

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number (if known): K090193

Device Name: Conductor Coronary Guidewire

Indications for Use:

For use in vascular interventional procedures to facilitate placement of catheters within the coronary arteries.

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachon

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K090193